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Commentary

Scientific Components in Standard Setting

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Although it has not, to my knowledge, been precisely articulated, one concept of the scientific component of determination of a standard is that, first, all relevant published data are collected; second, a process is undertaken to derive some consensus on the reliability or meaning of the research; and third, the resulting document is transmitted to those charged with recommending a standard. Such a description can now be seen, I wish to suggest, to be altogether too simplistic. It is not an adequate account of the necessary process, nor does it give any indication that the necessity to set some numerical standard has some interesting consequences, and also necessitates certain kinds of scientific activity which would not otherwise be undertaken.

The first reason for stating that this is the case has to do with the fact that a standard can be regarded as an ordinary scientific hypothesis—no different from the kind of hypothesis that evolves as a consequence of laboratory work. Admittedly, a standard has to be expressed as a hypothesis for this relationship to be obvious, but when it is written in the form "if no exposure above x ppm occurs, then no excess of certain events (such as cases of some specific condition) will be observed," the fact that a standard is a scientific hypothesis becomes evident. It will be found to satisfy all the criteria we have for a scientific hypothesis. In particular, it satisfies the requirement, set out in great detail by Sir Karl Popper, that it should be a falsifiable hypothesis. The interesting fact about a hypothesis of this kind is that its strength depends to a considerable extent on interaction of data from different disciplines, of which no one individual can claim to be a master. Hence, the statement of such a hypothesis requires a background of consistency which is not required to anything like the same degree with simpler kinds of hypothesis.

Second, all such standard setting brings us into immediate contact with a range of problems which are common to all questions concerning low level exposure, whether it be to asbestos, radiation or benzene. There are statistical problems with low dose effects which have recently been eloquently discussed by Land (*1*). These have to do with the problem of sample size and statistical significance when a reliable estimate of low level effects is required; and there are also some special methodological problems which are not encountered in ordinary scientific work. A good example from the field of air pollution research is the problem of the necessary requirement that large numbers of individuals must be studied if the earliest effects are to be detected; but on the other hand the larger the sample size the more imprecise is the exposure data. In a recent study which I have undertaken (*2*), we found that a population of 5.7 million people scattered in a corridor 250 miles long was necessary for there to be 40 acute respiratory admissions to hospitals per day. One needs about this number to detect, with any reliability, variations in hospital admission rate for these diseases which might be related to present air pollution levels. But it is obvious that one's knowledge of actual exposure levels is very imprecise under these circumstances, and this constraint is inherent in the methodology for examining low dose effects, particularly if one wants to study the effects of 24-hr variations in air pollution levels. There are, no doubt, other methodological problems which can be seen, as it were, to be "built in" to this kind of scientific problems. It seems obvious to me that many legislators have found it difficult to understand these limitations, often blaming the investigators for them, or, if a particular standard is being opposed, using these difficulties to suggest that all such studies are so unreliable that the result can be disregarded.

A third interesting component is that the need for a numerical standard of some kind raises a new type of question. We need not be apologetic that scientific activity has to be directed at practi-

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cal questions, since this has historically been true on many previous occasions. The idea that science is concerned only with what might be called "sui generis" questions dies hard, but I always find it satisfying to recall that one of the earliest items of business of the Royal Society in London in the late 17th century was to turn its attention to the then urgent problem of pumping water out of coal mines (*3*). A great deal of mechanical development was needed to solve this problem and was undertaken at that time. It formed the basis of much important technological advance and ultimately new scientific insights. The new types of questions which are raised are of many kinds, of which I may perhaps single out one as being of particular interest. Let us say that there is animal experimental evidence that if a small animal grows up in an atmosphere of an environmental contaminant at a time when the lung is developing and growing, there is some alteration in the mechanical characteristics of the lung observable when the animal has reached full growth. It would then become very important to make sure that children spending the first nine years of their lives, when alveoli are still being produced, are not adversely affected in some way for the rest of their lives if they breathe low levels of certain pollutants. Such a question necessarily draws our attention to the importance of understanding the components of normal lung development, and also being able to study different populations when lung growth is complete, to define "normality" in the absence of any environmental effects. I have always felt that the demonstration that lungs of dogs "age" in a certain characteristic way in the absence of any adverse environmental factors was an important scientific answer that bears on this kind of question. There may well be other instances—and the preservation of hearing may well be one of them—in which the highest level of preservation into old age does depend critically on an absence of sustained exposure during life. The need to define more accurately and in greater detail environmental effects necessarily draws attention to many of these areas of ignorance.

Fourth, the need for a numerical standard necessitates new requirements in the scientific field which are procedural rather than concerned with ideas and research. This, in a sense, the most obvious aspect of the scientific component of determining a standard, and if one generalizes the question then one can clarify to some extent the relevance of scientific tradition to its conduct. The first of these requirements is that all the scientific data needs to be reviewed. Ordinarily, in scientific work it would be rare for a graduate student or a scientist to be able to claim that every paper had been quoted, and even if his original manuscript contained the one thousand or so references which this would necessitate, no editor would publish them. With the standard-setting process, however, it is necessary that the data review be complete. It is not enough to exclude consideration of a paper even if you will later conclude that the information it contained should be disregarded. You have to give reasons why you hold such an opinion. The second and most difficult component in this area is that many different fields must be reviewed. What is being sought is consistency between experimental results with animal experimentation, which largely indicate mechanism or site of first effect; human exposure experiments, which may define the lowest level to cause some physiological change; and epidemiological evidence which should tell us whether or not any specific differences in symptoms, function or occurrence of defined illness, or mortality, are or are not related to environmental influences. In the case of some pollutants, of which I would consider ozone to be an example, all three fields show reasonable consistency at approximately the right level of gas concentration. In relation to other pollutants, of which some would say sulphur dioxide is an example, there is no satisfying consistency. Although the epidemiological evidence from so many different places showing some relationship between measured SO_2 levels and various phenomena seems to be coherent, the acute human exposure experiments do not demonstrate any significant effects at such low concentrations as are commonly encountered, and chronic animal exposures have never shown any significant effects even at much higher concentrations. To return to a point I made earlier, the strength of the hypothesis (which is contained within the standard) does depend at least to some extent on a consistency of observation across different fields of endeavor; and therefore in the formulation of the hypothesis for a standard, it is obviously necessary that all these different fields must be reviewed. This is a constraint which is not laid on the individual experimental scientist. Third, an interesting consequence of regulation as a whole is that it necessarily represents an activity in which there is a continuing and close juxtaposition between what are considered to be scientific "facts," and human "values." A detailed discussion of this aspect of the standard setting process would bring me directly to the point which I am not going to consider, namely, the process whereby this reconciliation is achieved, and a final judgment made in the light of the contemporary social, political, and I think one should properly say economic, climate of the times.

All of this activity indicates that the scientific components in standard setting are interesting in themselves, and that the whole process is rather different from the simplistic view I sketched originally. I think it does no harm to step back from the process and recognize the constraints and individual features as it may make some difficulties in what is being attempted, easier to overcome.

If you wish to regard a numerical standard as a scientific hypothesis, it would necessarily follow, I would suppose, that the tradition of science would require that a number of conditions be scrupulously observed. That the process should be open with a generality of input, and that evidence not be admitted or excluded for prior political or personal reasons, should be evident enough. That all the evidence should be thoroughly and diligently reviewed is, I have suggested, more important in relation to the scientific process of standard setting than it is in most ordinary scientific activities. A third aspect is the necessity for there to be a clear definition of where the evidence deducible from scientific data ends, and where some judgment has entered the discussion. I believe that scientists are becoming much better at making this differentiation, but it is obvious that in this field a clear perception of this point is of the greatest importance. Finally, when the whole process is complete, it should be possible to separate a standard which would have been determined if no economic factors were taken into account, from any final standard adopted which necessarily had to be based on economic, and to some extent political, expediency.

There are, of course, some aspects to the standard setting process which are much less satisfactory. I have recently received, for example, a very large comprehensive volume more than an inch thick, weighing several pounds, from a firm of Washington attornies not previously known to me. I am surprised to find within this a number of analyses of some work which I have published, presumably solicited on behalf of clients of the lawyers and, since the copy was sent to me, probably having wide circulation. One would have thought that it would be an important part of the legal tradition that before such comments were circulated, the individual concerned might have an opportunity to clarify some of the misconceptions which these comments contain, but presumably it is expected that a rebuttal of that kind would only take place in a legal forum where its weight could be properly assessed. Nevertheless, I think it is curious that such comments are freely circulated in a form in which comment, or perhaps I should say counter-comment, is not possible. I have to confess that I find reading these interesting. It tends to increase my respect for the scientific integrity of some of my colleagues, and diminishes it in the case of others.

I am not going to discuss whether we need numerical standards nor in detail the process by which we should arrive at them. However, it should be evident to you by now that by devoting some attention to what is involved in the process, I have in a sense revealed my opinion as to the necessity of such standards. Difficult though it may be to arrive at them, and complex and expensive although the process will be to determine them, I feel about them much as Winston Churchill felt about democratic government, namely that we can recognize its faults, but we do not know of any better alternative. I have never been sympathetic to the view, which seems to be popular in Britain, that because, in their opinion, the setting of any standard is so dissociated from what, in their opinion, constitutes science, that no one should attempt it. I consider this to be a lazy approach to the problem of public health protection, and I hope that the benefits of attempting to set a standard will in the end be seen to be greater than the penalties of not attempting to do so. Though such a position could not, thank goodness, be quantitated in economic terms, I think it is a position to which most sensible men would subscribe (*4*).

REFERENCES

1. Land, C. E. Estimating cancer risks from low doses of ionizing radiation. Science 209: 1197-1203 (1980).
2. Bates, D. V., and Sizto, R. Relationship between air pollutant levels and hospital admissions in Southeastern Ontario. Can. J. Publ. Health 74: 117-122 (1983).
3. Merton, R. K. Science, Technology and Society in Seventeenth-Century England. Harper & Row, New York, 1970.
4. Bates, D. V. Air Pollution; political initiative, scientific reality and the process of decision-making. Lung 156: 87-94 (1979).